UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,185	12/14/2000	Danny Charles Bowman	2552-011	9139

4678 7590 10/11/2011

MACCORD MASON PLLC
300 N. GREENE STREET, SUITE 1600
P. O. BOX 2974
GREENSBORO, NC 27402

EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1777	

MAIL DATE	DELIVERY MODE
10/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/737,185	BOWMAN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-21,38 and 40-49* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-21,38 and 40-49* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/13/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____ .

DETAILED ACTION

1. Amendment filed on 07/18/11 is acknowledged. Claims 1-21, 38 and 40-49 are pending in the application.

Response to Amendment

2. The amendment filed 07/18/11 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a diagnostic system comprising a plurality of biomedical specimen collection vessels, at least some members of the plurality being located at a vessel distribution facility, other members of the plurality being located at a specimen collection facility, further members of the plurality being located at a specimen testing laboratory facility, and additional members of the plurality being transported between the facilities,".

Applicant is required to cancel the new matter in the reply to this Office Action. The recitation of claim 1 completely contradicts the specification, as originally filed, since Figure 4 depicts moving of the specimen containers from one site to another site with no distribution of the "plurality of biomedical specimen collection vessels" among these sites. No term "plurality" of biomedical specimen vessels appears in the specification as originally filed.

3. The Affidavits filed on 07/18/11 under 37 CFR 1.131 are sufficient to overcome the Abrams reference.

4. Affidavit filed on 06/17/04 under 37 CFR 1.131 is not proper, since the same subject matter is claimed in the instant application and in Petrick's patent (US 6,535,129), when the claims are read in light of the specification. Therefore only invoking interference is proper in this case.

5. The examiner re-establishes rejections which have been presented before the Board of Appeals and have never been considered by the Board, with the necessary corrections indicated in the remand. Also, additional prior art has been applied.

Double Patenting

6. Applicant is advised that should claims 1-8 be found allowable, claims 9-17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. A. Claims 1-17, 40-42, 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels, with at least some members of the plurality located at a vessel distribution facility, a collection facility, a specimen testing laboratory facility. The recitation of the claims contradicts the disclosure as originally filed. Not only the specification does not have the term "plurality of the vessels" or any of its equivalent, but the only disclosure regarding distributing plurality of vessels is related to Figure 4, according to which the plurality of vessels is moving *from* one facility *to* another. No distribution of the plurality of vessels among indicated facilities is disclosed in the specification. On the contrary, according to Figure 4, there are no times, when such distribution among facilities occurs.

B. Claims 1-21, 38 and 40-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "electronic memory tag", which is a broad definition. In particular, electronic memory tags are described in US 7,032,822: "[a] memory tag has a non-volatile memory in which in use data is stored, an antenna coil and power supply circuit such that in use the memory tag is powered by inductive coupling. The memory tag also has a sensor for

receipt of transmitted light carrying input signals and a processor for processing of the received input signals, and a modulation circuit for overlay of output signals onto the power supply circuit. A read/write device, for communication with the memory tag has a signal generator, an antenna coil and a power supply circuit for powering the memory tag in use by inductive coupling." The specification does not disclose anything similar to the description of the "electronic memory tag" from the patent. Furthermore, the RFID tags disclosed in specification from the various patents are not adjusted for using with the collection vessels. The art related to RFID tags which can be used with collection vessels appears after 2005, e.g. see the article "Calif. Startup Develops RFID-enabled Products to Track Medical Tests ": "Smart Medical Technologies' line of RFID-enabled test tubes, vials and other containers incorporates proprietary 13.56 MHz tags that can store up to 4 kilobytes of data." (Abstract). Also, as the article by Uddin et al. "UHF RFID antenna architectures and applications" (Scientific Research and Essays, 2010), indicates, using RFID tags for vials with liquids require specific adjustment of antenna and RFID field in RFID tags: "[e]arly UHF tags occasionally encountered problems around materials like metal and liquids." Such tags, which have been specifically designed for using in vials were not disclosed in the instant disclosure.

The examiner respectfully reminds the Applicants that according to MPEP §2163:

"**2163.02. Standard for Determining Compliance with Written Description Requirement**:

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures,

> diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The Applicants did not show "possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention".

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 38 and 40-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Several claims recite "[a] diagnostic specimen system comprising a plurality of biomedical specimen collection vessels, at least some members of the plurality being located at a vessel distribution facility, other members of the plurality being located at a specimen collection facility, further members of the plurality being located at a specimen testing laboratory facility, and additional members of the plurality being transported between the facilities". First, the claim language is not supported by the specification, and it is not apparent, how this system is formed. Is this a permanent system, or is this a changing system? Are these vessels constantly located at the indicated facilities? Are the vessels located at recited facilities different from each other? The language renders the claims unclear and indefinite.

Furthermore, the claims recite that each of the collection vessel includes a wireless electronic memory tag, directly attached to the vessel. First, it is not clear, which specific "electronic memory tag" is meant in the claims, since there are various electronic memory tags, which are designed for different purposes. It is not clear, whether there is a specific electronic

memory tag, which is designed to be used for the biological vessels. Further, it is not clear, what it means "directly attached". The electronic memory tag disclosed in the specification is described as comprising a carrier label (4) which has a front face (5) and a rear face (6) with the electronic memory device (9) attached to the rear face. Therefore, it is not apparent what specifically is "directly attached" to the vessel - the label with the electronic memory device? Furthermore, the electronic memory device (9) is described as an ultra-thin radio frequency transponder made up of an integrated circuit and an antenna. However, Uddin et al. in "UHF RFID antenna architectures and applications" demonstrates that developing antenna for the specific purpose is not a trivial task. Therefore, it is not apparent, which specific "electronic memory tag" is recited in the claims, which renders them unclear and indefinite.
The Applicants are respectfully referred to the following excerpt from MPEP:

> "§2171 **Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph:**
>
> The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
>
> There are two separate requirements set forth in this paragraph:
> (A) the claims must set forth the subject matter that applicants regard as their invention; and
> (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.
>
> The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.
>
> Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.
>
> The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner

should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 Bd. App. 1984)"

Furthermore:

"§2172 **Subject Matter Which Applicants Regard as Their Invention:**

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)."

In the instant case "the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement", and therefore rejection under 35 U.S.C. 112, second paragraph, is appropriate.

In claims 4 and 12 it is not clear, whether the label is the same label that includes the electronic memory device, as disclosed in the specification.

From claims 6-7 and 14-15 it is not apparent, whether the vessel contains a specimen.

From claim 38 it is not clear, where "a tamper-indicating seal" is located on the vessel. This is an essential structural relation omitted from the claim.

Claim 40 is not clear. What does it mean - "an electronic database accessible from the specimen collection facility for storing data entered at the collection facility"? It is accessible for what? The recitation of the claim is not quite clear.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129 B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record

tagged to the RFID chip" (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

12. **Claims 1, 6-7, 9, 14-15, 19, 21 and 40-41** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. … It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are

no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

"A population of "biomedical specimen collection with "members" located at various locations of the specimen path is an inherent feature of the invention. As soon as the tag becomes attached to the test tube, the location where it occurs becomes "a distribution facility". Attaching the tag with all information should occur before collection of the sample into the vessel. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The situation, when the tubes are used for collecting samples without providing any information related to the sample and "the person under concern" (col. 1, line 68) seems improbable. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously. Moving the test tubes from the collection facility (a desk where the samples are taken) to the analysis site is what Barney discloses for his population of the test specimen tubes with electronic tags.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. **Claims 5, 8, 13 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Petrick and Barney is provided above.

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who

discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

15. **Claims 16-17, 20 and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Petric and Barney is provided above.

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates "tester's signature" in form 102, Fig. 3B. The signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

16. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

The disclosure of Barney is provided above.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

17. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

The disclosure of Barney is provided above.

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

18. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

The disclosure of Barney is provided above.

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

19. **Claim 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

The disclosure of Barney is provided above.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of

the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

20. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

21. **Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of paper by Moore (December 1999).

Stevens discloses a plurality of collection containers with a partitioned specimen label, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Stevens does not disclose electronic tag memory.

Moore in his article "Barcodes, 2D or RFID?" specifically indicates: "This is not a contest between technologies. Barcodes, two-dimensional (2D) symbols and RFID smart labels may compliment each other in everyday use. We already see examples of linear and 2D symbols being used for different purposes on the same label." "Radio frequency identification (RFID) has long been viewed as the most significant alternative to barcode technology. It has made major incursions into manufacturing and transportation for identifying and tracking of items during harsh manufacturing processes as well as for vehicle identification of over-the-road trucks, trailers, intermodal containers and railroad rolling stock. Recent advancements in the technology, however, have reduced the size and cost of RFID tags from over $100 in many cases to about $50. The new generation of printing and reading equipment is also smaller, lighter and much more cost-effective for labels than was previously available. So-called smart labels have an

inexpensive RFID chip embedded in a self-adhesive paper label (other form factors would also be possible). The label would typically have at least one barcode on it and the RFID chip would be encoded at the same time the barcode and human-readable information is printed on the label. A lot of attention is being focused on smart labels because of their potential to carry complete electronic manifests and packing lists as well as a full range of other information, some of which can be used for tracking."

Thus, Moore specifically emphasizes benefits of using smart labels having an inexpensive RFID chip embedded in a self-adhesive paper label (other form factors would also be possible). "The label would typically have at least one barcode on it and the RFID chip would be encoded at the same time the barcode and human-readable information is printed on the label". This allows a direct modification of Stevens' two-partition barcode with attaching RFID chip to the permanent affixed portion of the label. Such modification will also be tamper-indicating.

Since the tubes with the labels will be manufactured, they will be inherently distributes between all facilities of custody chain for the biological sample collection tubes.

22. **Claims 5, 8, 13 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of paper by Moore, as applied to claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Stevens in view of Moore is provided above.

Although Stevens in view of Moore do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because

information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for modified Stevens' test tubes, which are specifically designed for handling such information.

23. **Claims 16-17, 20 and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Moore, as applied to claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49 above, and further in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Stevens in view of Moore is provided above.

Stevens in view of Moore do not particularly teach encoding electronic signature in the electronic tag.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into modified Stevens' system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Response to Arguments

24. Applicant's arguments with respect to claims 1-21, 38 and 40-49 have been considered but are moot in view of the new ground(s) of rejection.

Nevertheless, the examiner would like to address two issues which are still applicable to the present Office action.

Regarding the word "plurality" *vs.* the word "population" it appears that the Applicants misunderstood the examiner's point. The examiner indicated the following:

> "The claims recite a diagnostic specimen system comprising a population of biomedical specimen collection vessels, with at least some members of the population located at a vessel distribution facility, a collection facility, a specimen testing laboratory facility. The recitation of the claims contradicts the disclosure as originally filed. Not only the specification does not have the term "population of the vessels" or any of its equivalent, but the only disclosure regarding distributing plurality of vessels is related to Figure 4, according to which the plurality of vessels is moving from one facility to another. ***No distribution of the plurality of vessels among indicated facilities is disclosed in the specification***. On the contrary, according to Figure 4, there are no times, when such distribution among facilities occurs."

Regarding the newly acquired knowledge of the examiner which modifies her position, the examiner did not apply the references published in 2006 and 2010 as the prior art, and therefore the arguments that these references have been published after the filing date of the instant application and thus are improper are not applicable. The examiner has the right to apply such newly found or published art under 35 U.S.C. 112, first paragraph, rejections. The rejection did not require that the Applicants have disclosed later-inventive things. Quite the contrary, the examiner specifically indicated that the claimed subject matter has not been in possession of the Applicants specifically because only the latest development of the technology enabled the invention, with the idea itself totally obvious to any routineer in the art.

As to the "moving" issue and drawing an analogy with Edisons' electrical light, the examiner considers analogy of the moving identical containers from one place to another not quite analogous to the burning filament of Edisons' electrical bulb. Rather the closer analogy would be Edison's invention of a plurality of bulbs which are placed in different locations and are transported from e.g. their production site to e.g. the store, and from there – to the customers' homes. Furthermore, according to the Applicants presentation of the claims this Edison's invention would be patentably distinct from the one that he in fact obtained, namely the electrical

bulb. As to the changing status of the vessels – the examiner considers the analogy of the short-lived iPhone (specifically, longer-living iPhone 4) in comparison to the life of the old universe is not quite correct as well. It is quite possible that the vessels of the instant invention will live as long as the Earth itself. So, their status as entities will not change for quite some time. However, the system of constantly moving vessels with unknown number of vessels, some of which are dropped at some places while others are moving to other places, does not seem to be quite definite.

As to the definition of the "electronic memory tag", which is in fact an RFID chip attached to the label, the Applicants in the past had quiet lengthy arguments that this electronic memory tag is not equivalent to the Patrick's business form, which is the label with the attached RFID chip. Therefore, the examiner's question has been induced by the Applicants' arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571)272-1257. The examiner can normally be reached on 9:30am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh, Ph.D./
Primary Examiner, Art Unit 1777

10/3/2011